Receipt date: 11/07/2006 10595076 - GAU: 1649

Docket No.: 05558.0036.PCUS00

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):

Bengt-Ake Bengtsson

Title:

USE OF HUMAN GROWTH HORMONE IN

MULTIPLE SYSTEM ATROPHY

App. No.:

10/595,076

Conf. No.:

2186

**.** 

Art Unit: Not Yet Assigned

Filing Date:

July 29, 2003

Examiner: Not Yet Assigned

## INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. §§ 1.56, 1.97 AND 1.98

MAIL STOP AMENDMENT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## Dear Sir:

In compliance with 37 C.F.R. § 1.97 and the continuing duty of disclosure under 37 C.F.R. § 1.56, Applicants call to the attention of the Examiner the references listed on the attached Forms PTO/SB/08A and PTO/SB/08B. It is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Forms PTO/SB/08A and PTO/SB/08B be considered by the Examiner and made of record.

In accordance with 37 C.F.R. § 1.97(g), this Information Disclosure Statement is not to be construed as a representation that a search has been made. In accordance with 37 C.F.R. § 1.97(h), this Information Disclosure Statement is not to be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

This Information Disclosure Statement does not include copies of cited U.S. patents and U.S. patent publications pursuant to 37 C.F.R. 1.98(a)(2).

This Information Disclosure Statement is being filed prior to the receipt of a first Office Action reflecting an examination on the merits, and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b)(3).

Receipt date: 11/07/2006 10595076 - GAU: 1649

Application No.: 10/595,076 Docket No.: 05558.0036.PCUS00

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to this document, the Commissioner is hereby authorized to deduct the fees from Howrey Simon Arnold & White, LLP Deposit Account 08-3038.

Respectfully submitted,

HOWREY LLP

Dated: November 7, 2006 By:

David W. Clough, Ph.D. Registration No.: 36,107 Customer No.: 22930

HOWREY LLP 321 N. Clark Street, Suite 3400 Chicago, IL 60610 (312) 595-1239 (main) (312) 595-1408 (direct) (312) 595-2250 (fax)

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PTO/SB/08a (07-06)

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Complete if Known Substitute for form 1449A/PTO 10/595,076 Application Number INFORMATION DISCLOSURE Filing Date July 29, 2003 STATEMENT BY APPLICANT First Named Inventor Bengt-Ake Bengtsson 1646 Art Unit **Examiner Name** Not yet assigned (Use as many sheets as necessary) 3 Attorney Docket Number 05558.0036.PCUS00 Sheet

Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2 (if known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1	Re 33,653	07/30/1991	Mark, et al.	
	A2	4,588,585	05/13/1986	Mark,et al.	
	А3	4,737,462	04/12/1988	Mark, et al.	
	A4	4,904,584	02/27/1990	Shaw	
	A5	4,959,314	09/25/1990	Mark, et al.	
	A6	4,965,195	10/23/1990	Namen, et al.	
	Α7	5,017,691	05/21/1991	Lee, et al.	
	A8	5,116,943	05/26/1992	Koths, et al.	
	A9	5,137,872	08/11/1992	Seely, et al.	
	A10	5,534,617	07/09/1996	Cunningham, et al.	
	A11	5,597,709	01/28/1997	Rosen, et al.	
	A12	5,612,470	03/18/1997	Thorner, et al.	
	A13	5,633,352	05/27/1997	Dalboge, et al.	
	A14	5,635,604	06/03/1997	Dalboge, et al.	
	A15	5,654,010	08/05/1997	Johnson, et al.	
	A16	5,688,666	11/18/1997	Bass, et al.	
	A17	5,696,089	12/09/1997	Felix, et al.	
	A18	5,721,250	02/24/1998	Morriello, et al.	
	A19	5,721,251	02/24/1998	Chen, et al.	
	A20	5,723,616	03/03/1998	Houghton, et al.	
	A21	5,726,307	03/10/1998	Schoen, et al.	
	A22	5,726,319	03/10/1998	Lin, et al.	

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 'Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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s	Substitute for form 1449A/PTO			Complete if Known			
				Application Number	10/595,076		
	NFORMATION DISC	CLC	SURE	Filing Date	July 29, 2003		
5	STATEMENT BY AF	PL	CANT	First Named Inventor	Bengt-Ake Bengtsson		
				Art Unit	1646		
	(Use as many sheets as nec	essary	)	Examiner Name	Not yet assigned		
Sheet	2	of	3	Attorney Docket Number	05558.0036.PCUS00		

Examiner Initials*	Cite No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee Applicant of Cited Doo		Pages, Columns, Lines, Where Relevant Passages or Relevant
	1	Number-Kind Code <sup>2 (if known)</sup>				Figures Appear
	A23	5,731,317	03/24/1998	Lu, et al.		
	A24	5,736,515	04/07/1998	Bengtsson, et al.		
	A25	5,767,085	06/16/1998	Johansen, et al.		
	A26	5,767,118	06/16/1998	Nargund, et al.		
	A27	5,767,124	06/16/1998	Draper, et al.		
	A28	5,773,441	06/30/1998	Hipskind, et al.		
	A29	5,776,901	07/07/1998	Bowers, et al.		
	A30	5,777,112	07/07/1998	Nargund, et al.		
	A31	5,792,747	08/11/1998	Schally,et al.		
	A32	5,795,957	08/18/1998	Deghenghi		
	A33	5,798,337	08/25/1998	Somers, et al.		
	A34	5,804,578	09/08/1998	Chakravarty, et al	_	
	A35	5,807,985	09/15/1998	Deghenghi		
	A36	5,830,433	11/03/1998	Dean, et al.		
	A37	5,834,598	11/10/1998	Lowman, et al.		
	A38	5,843,453	12/01/1998	Holder, et al.		
	A39	5,846,936	12/08/1998	Felix, et al.		
•	A40	5,847,066	12/08/1998	Coy, et al.		·
	A41	5,849,535	12/15/1998	Cunningham, et a	I.	
	A42	5,849,700	12/15/1998	Sorensen, et al.		
	A43	5,849,704	12/15/1998	Sorensen, et al.		
*****	A44	5,851,992	12/22/1998	Sorensen		
	A45	5,869,452	02/09/1999	Ng, et al.		
	A46	6,143,523	11/07/2000	Cunningham, et a	I.	
	A47	6,335,319	01/01/2002	Ng, et al.		
Examiner Signature		/Christina Borgeest/	(04/03/2009)	F "	ate Considered	

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Complete if Known Substitute for form 1449A/PTO 10-595,076 Application Number INFORMATION DISCLOSURE July 29, 2003 Filing Date STATEMENT BY APPLICANT First Named Inventor Bengt-Ake Bengtsson Art Unit 1646 Not yet assigned **Examiner Name** (Use as many sheets as necessary) 05558,0036,PCUS00 3 Attorney Docket Number Sheet

		FOREIGN F	PATENT DOC	JMENTS		
Examiner Initials*	Cite No.	Foreign Patent Document  Country Code <sup>3</sup> "Number <sup>4</sup> "Kind Code <sup>5</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	<b>T</b> 6
	B1	WO 00/42175	07/20/2000	Bolder Biotechnology Inc.		
	B2	WO 02/17951	03/07/2002	Colorado State University Research Foundation		
	ВЗ	WO 02/28437	04/11/2002	Ares Trading S.A.		
	В4	WO 91/09955	07/11/1991	Applied Research Systems, ARS Holding MV		
	B5	WO 97/21449	06/19/1997	Colorado State University Research Foundation		
	В6	WO 99/12969	03/18/1999	Metabolic Pharmaceuticals Ltd.		
Examiner Signature		/Christina Borgeest/ (04/03/2	2009)	Date Considered		

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10595076 - GAU: 1649

PTO/SB/08B (08-03)

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Subst	titute for forn	1449/	РТО	Complete if Known		
I	NFORMA	TIO	N DISCLOSURE	Application Number	10/595,076	
			BY APPLICANT	Filing Date	July 29, 2003	
			eets as necessary)	First Named Inventor	Bengt-Ake Bengtsson	
	(Ose as ii	iany sin	sets as necessary)	Group Art Unit	1646	
				Examiner Name	Not yet assigned	
Sheet	1	of	8	Attorney Docket Number	05558.0036.PCUS00	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, scrial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	T²
	C1	Aberg, N. David, et al., "Growth Hormone Increases Connexin-43	
		Expression in the Cerebral Cortex and Hypothalamus*," Endocrinology,	
		Vol. 141, No. 10, pp. 3879-3886 (2000)	
	C2	Adelman, J. P., et al., "In Vitro Deletional Mutagenesis for Bacterial	
		Production of the 20,000-Dalton Form of Human Pituitary Growth	
		Hormone," DNA (N.Y.), Vol. 2, No. 3, pp. 183-193 (1983)	
	C3	Alba-Roth, J., et al., "Arginine Stimulates Growth Hormone Secretion by	
		Suppressing Endogenous Somatostatin Secretion," Journal of Clinical	
		Endocrinology and Metabolism, Vol. 67, No. 6, pp. 1186-1189 (1988)	
	C4	Albertsson-Wikland, K., et al., "Daily Subcutaneous Administration of	
		Human Growth Hormone in Growth Hormone Deficient Children," Acta	
		Paediatr Scand, Vol. 75, pp.89-97 (1986)	
	C5	Altschul, S. F., et al., "Basic Local Alignment Search Tool," J. Mol. Biol., Vol. 215, pp. 403-410 (1990)	
	C6	Altschul, S. F., et al., "Gapped BLAST and PSI-BLAST: A New Generation	
		of Protein Database Search Programs," Nucleic Acids Research, Vol. 25,	
		No. 17, pp. 3389-3402 (1997)	
	C7	Andersson, K., et al., "Rat Growth Hormone and Hypothalamic	
		Catecholamine Nerve Terminal Systems, Evidence for Rapid and Discrete	
		Reductions in Dopamine and Noradrenaline Levels and Turnover in the	
		Median Eminence of the Hypophysectomized Male Rat," European Journal	
		of Pharmacology, Vol. 95 pp. 271-275 (1983)	
	C8	Bandmann, O., et al., "Multiple-System Atrophy is Genetically Distinct	
		from Identified Inherited Causes of Spinocerebellar Degeneration,"	
		Neurology, Vol. 49, pp. 1598-1604 (1997)	
	C9	Becker, G. W., et al., "Isolation and Characterization of a Sulfoxide and a	
		Desamido Derivative of Biosynthetic Human Growth Hormone,"	
		Biotechnology and Applied Biochemistry, Vol. 10, pp. 326-337 (1988)	

Examiner	/Christina Rorgeost/ (04/03/2009)	Date	
Signature	/Cnristina Borgeest/ (04/03/2009)	Considered	

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\*AMMINER: Infinial if reference considered, whether or not chatton is in conformance with MPPP 809. Draw line through chatton if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449/PTO	Comp	lete if Known
INFORMATION DISCLOSURE	Application Number	10/595,076
STATEMENT BY APPLICANT	Filing Date	July 29, 2003
	First Named Inventor	Bengt-Ake Bengtsson
(Use as many sheets as necessary)	Group Art Unit	1646
	Examiner Name	Not yet assigned

Attorney Docket Number

f		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	T²
	C10	Bewley, T. A., et al., "Sequence Comparison of Human Pituitary Growth Hormone, Human Chorionic Somatomammotropin, and Ovine Pituitary Growth and Lactogenic Hormones," Int. J. Peptide Protein Res., Vol. 4, pp. 281-287 (1972)	
	C11	Bowers, C. Y., et al., "On the Actions of the Growth Hormone-Releasing Hexapeptide, GHRP*," Endocrinology, Vol. 128, No. 4, pp. 2027-2035 (1991)	
	C12	Burman, P., et al., "Quality of Life in Adults with Growth Hormone (GH) Deficiency: Response to Treatment with Recombinant Human GH in a Placebo-Controlled 21-Month Trial," Journal of Clinical Endocrinology and Metabolism, Vol. 80, No. 12, pp. 3585-3590 (1995)	
	C13	Camanni, F., et al., "Growth Hormone-Releasing Peptides and Their Analogs," Frontiers in Neuroendocrinology, Vol. 19, pp. 47-72 (1998)	
	C14	Chen, E. Y., et al., "The Human Growth Hormone Locus: Nucleotide Sequence, Biology, and Evolution," Genomics, Vol. 4, pp. 479-497 (1989)	
	C15	Daniel, S. E., "The Neuropathology and Neurochemistry of Multiple System Atrophy," Mathias CJ, Bannister R eds. Autonomic Failure: A Textbook of The Autonomic Nervous System, 4 <sup>th</sup> ed., Oxford University Press, pp. 321-328 (1999)	
	C16	DeNoto, F., et al., "Human Growth Hormone DNA Sequence and mRNA Structure: Possible Alternative Splicing," Nucleic Acids Research, Vol. 9, No. 15, pp. 3719-3730 (1981)	
	C17	Devereux, J., et al., "A Comprehensive Set of Sequence Analysis Programs for the VAX," Nucleic Acids Research, Vol. 12, No. 1, pp. 387-395 (1984)	
	C18	Eecken, H. V., et al., "Striopallidal-Nigral Degeneration, An Hitherto Undescribed Lesion in Paralysis Agitans," American Association of Neuropathologists, Vol. 19, pp. 159-161 (1960)	

Examiner	(Chainting Down and (04/00/0000)	Date	
Signature	/Christina Borgeest/ (04/03/2009)	Considered	

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a collection of information unless it contains a valid CARP contains.

Substitute for form 1449/PTO	Complete if Known		
INFORMATION DISCLOSURE	Application Number	10/595,076	
STATEMENT BY APPLICANT	Filing Date	July 29, 2003	
	First Named Inventor	Bengt-Ake Bengtsson	
(Use as many sheets as necessary)	Group Art Unit	1646	
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Sheet 3 of 8	Attorney Docket Number	05558.0036.PCUS00	

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	C19	Felix, A. M., et al., "Pegylated Peptides IV Enhanced Biological Activity of Site-Directed Pegylated GRF Analogs," Int. J. Peptide Protein Res., Vol. 46, pp. 253-264 (1995)	
	C20	Friend, K., et al., "Pyridostigmine Treatment Selectively Amplifies the Mass of GH Secreted per Burst Without Altering GH Burst Frequency, Half-Life, Basal GH Secretion or the Orderliness of GH Release," European Journal of Endocrinology, Vol. 137, pp. 377-386 (1997)	
	C21	Gertler, A., et al., "Inhibition of Lactogenic Activities of Ovine Prolactin and Human Growth Hormone (hGH) by a Novel Form of a Modified Recombinant hGH*," Endocrinology, Vol. 118, No. 2, pp. 720-726 (1985)	
	C22	Ghigo, E., et al., "Orally Active Growth Hormone Secretagogues: State of the Art and Clinical Perspectives," Annals of Medicine Vol. 30, pp. 159-168 (1998)	
	C23	Gilman, S., et al., "Consensus Statement on the Diagnosis of Multiple System Atrophy," Journal of the Autonomic Nervous System, Vol. 74, pp. 189-192 (1998)	
	C24	Goeddel, D. V., et al., "Direct Expression in <i>Escherichia coli</i> of a DNA Sequence Coding for Human Growth Hormone," Nature, Vol. 281, pp. 544-548 (1979)	
	C25	Graft, L., et al., "Human Somatotropin," The Journal of Biological Chemistry, Vol. 257, No. 5, pp. 2365-2369 (1982)	
	C26	Grantham, R., "Amino Acid Difference Formula to Help Explain Protein Evolution," Science, Vol. 185, pp.862-864 (1974)	
	C27	Harvey, S., et al., "Growth Hormone: Neurocrine and Neuroendocrine Perspectives," Growth Regulation, Vol. 3, pp. 161-171 (1993)	

Examiner   Date   Christina Borgeest/ (04/03/2009)   Considered   Cons			<del></del>	
	Examiner	(0) (1) (0) (0) (0)	Date	
Olganitus /	Signature	/Gninsuna borgeesi/ (04/03/2009)	Considered	

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10595076 - GAU: 1649

PTO/SB/08B (08-03)

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Subst	itute for form	1449/	PTO	Complete if Known		
T	NFORMA	TIO	N DISCLOSURE	Application Number	10/595,076	
			BY APPLICANT	Filing Date	July 29, 2003	
				First Named Inventor	Bengt-Ake Bengtsson	
	(Ose as m	any sm	eets as necessary)	Group Art Unit	1646	
				Examiner Name	Not yet assigned	
Sheet	4	of	8	Attorney Docket Number	05558.0036.PCUS00	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	T²
	C28	Holmberg, B., et al., "Increased Cerebrospinal Fluid Levels of	
		Neurofilament Protein in Progressive Supranuclear Palsy and Multiple-	
		System Atrophy Compared with Parkinson's Disease," Movement	
		Disorders, Vol. 13, No. 1, pp. 70-77 (1998)	
	C29	Hsiung, H. M., et al., "Use of Bacteriocin Release Protein in E. Coli For	
		Excretion of Human Growth Hormone into the Culture Medium,"	
		Biotechnology, Vol. 7, pp. 267-271 (1989)	
	C30	Hughes, A. J., et al., "Apomorphine Test to Predict Dopaminergic	
		Responsiveness in Parkinsonian Syndromes," The Lancet, Vol. 336, pp. 32-34 (1990)	
	C31	Hughes, A. J., et al., "Challenge Tests to Predict the Dopaminergic	
		Response in Untreated Parkinson's Disease," Neurology, Vol. 41, pp. 1723-1725 (1991)	
	C32	Hughes, A. J., et al., "The Dopaminergic Response in Multiple System	
		Atrophy," Journal Of Neurology, Neurosurgery, and Psychiatry, Vol. 55, pp. 1009-1013 (1992)	
	C33	Johansson, J-O., et al., "Growth Hormone and Psychosocial and Central	
		Nervous Effects," Growth Hormone in Adults-Physiological and Clinical	
		Aspects, 2 <sup>nd</sup> edition, Cambridge University Press, pp. 349-372 (2000)	
	C34	Jorgensen, K. D., et al., "Pharmacokinetics of Biosynthetic and Pituitary	
		Human Growth Hormones in Rats," Pharmacology & Toxicology, Vol. 63,	
		pp. 129-134 (1988)	
	C35	Kimber, J. R., et al., "Distinction of Idiopathic Parkinson's Disease from	
		Multiple-System Atrophy by Stimulation of Growth-Hormone Release with	
	026	Clonidine," The Lancet, Vol. 349, pp. 1877-1881 (1997)	
	C36	Kimber, J., et al., "Physiological, Pharmacological and Neurohormonal	
		Assessment of Autonomic Function in Progressive Supranuclear Palsy,"	·
		Brain, Vol. 123, pp. 1422-1430 (2000)	اا

Examiner		Date	
Signature	/Christina Borgeest/ (04/03/2009)	Considered	

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	-			First Named Inventor	Bengt-Ake Bengtsson	
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	C37	Klein, C., et al., "The 'Cold Hands Sign' in Multiple System Atrophy,"	
		Movement Disorders, Vol. 12, No. 4, pp. 514-518 (1997)	
	C38	Kraft, E., et al., "The Combination of Hypointense and Hyperintense Signal	
		Changes on T <sub>2</sub> . Weighted Magnetic Resonance Imaging Sequences,"	
		Archives of Neurology, Vol. 56, pp. 225-228 (1999)	
	C39	Lewis, et al., "Hyperglycemic Activity of Growth Hormone,"	
		Endocrinology, Vol. 101, No. 5, pp. 1588-1603 (1977)	
	C40	Lewis, U. J., et al., "A Naturally Occurring Structural Variant of Human	
		Growth Hormone*," The Journal of Biological Chemistry, Vol. 253, No. 8, pp. 2679-2687 (1978)	
	C41	Lewis, U. J., et al., "Altered Proteolytic Cleavage of Human Growth	
		Hormone as a Result of Deamidation*," The Journal of Biological	l
		Chemistry, Vol. 256, No. 22 pp. 11645-11650 (1981)	
	C42	Lewis, U. J., et al., "Human Growth Hormone: Additional Members of the	
		Complex," Endocrinology, Vol. 104, No. 5, pp. 1256-1265 (1979)	
	C43	Lewis, U. J., et al., "The 20,000-Dalton Variant of Human Growth	
		Hormone: Location of the Amino Acid Deletions," Biochemical and	
		Biophysical Research Communications, Vol. 92, No. 2, pp. 511-516 (1980)	
	C44	Litvan, I., et al., "Clinical Research Criteria for the Diagnosis of Progressive	
		Supranuclear Palsy (Steel-Richardson-Olszewski Syndrome): Report of the	
		NINDS-SPSP International Workshop," Neurology, Vol. 47, pp. 1-9 (1996)	
	C45	Litvan, I., et al., "What Is the Accuracy of the Clinical Diagnosis of	
		Multiple System Atrophy?" Archives of Neurology, Vol. 54, pp. 937-944	
	CAC	(1997)	
	C46	Martial, J. A., et al., "Human Growth Hormone: Complementary DNA Cloning and Expression in Bacteria," Science, Vol. 205, pp. 602-607 (1979)	
	C47	Meinkoth, J., et al., "Hybridization of Nucleic Acids Immobilized on Solid	
	~ · ·	Supports," Analytical Biochemistry, Vol. 138, pp. 267-284 (1984)	

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Signature	/Christina Borgeest/ (04/03/2009)	Considered	

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Subs	stitute for form	1449/PTO		Comple	ete if Known
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		NT BY APP		Filing Date	July 29, 2003
				First Named Inventor	Bengt-Ake Bengtsson
(Use as many sheets as necessary)				Group Art Unit	1646
				Examiner Name	Not yet assigned
Sheet	6	of 8		Attorney Docket Number	05558.0036.PCUS00

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	C48	Moore, J. A., et al., "Equivalent Potency and Pharmacokinetics of Recombinant Human Growth Hormones With or Without an N-Terminal Methionine," Endocrinology, Vol. 122, No. 6, pp. 2920-2926 (1988)	
	C49	Pearson, W. R., "Rapid and Sensitive Sequence Comparison with FASTP and FASTA," Methods in Enzymology, Vol. 183, pp. 63-99 (1990)	
	C50	Pearson, W. R., et al., "Improved Tools for Biological Sequence Comparison," Proc. Natl. Acad. Sci. USA, Vol. 85, pp. 2444-2448 (1988)	
	C51	Polo, K. B., et al., "Botulinum Toxin-A Improves the Rigidity of Progressive Supranuclear Palsy," Annals of Neurology, Vol. 35, pp. 237-239 (1994)	
	C52	Quinn, N, "Multiple System Atrophy—The Nature of The Beast," Journal of Neurology, Neurosurgery, and Psychiatry. Special Supplement, pp.78-89 (1989)	
	C53	Raizada, M. K., et al., "The Role of Insulin-Like Growth Factors in the Nervous System," Annals of the New York Academy of Sciences, Vol. 692, pp. 10-21 (1993)	
	C54	Rosengren, L. E., et al., "A Sensitive ELISA for Glial Fibrillary Acidic Protein: Application in CSF of Adults," Journal of Neuroscience Methods, Vol. 51, pp. 197-204 (1994)	
	C55	Rosengren, L. E., et al., "Glial Fibrillary Acidic Protein in CSF of Multiple Sclerosis Patients: Relation to Neurological Deficit," Journal of the Neurological Sciences, Vol. 133, pp. 61-65 (1995)	***
	C56	Rosengren, L. E., et al., "Neurofilament Protein Levels in CSF are Increased in Dementia," Neurology, Vol. 52, pp. 1090-1093 (1999)	
	C57	Rosengren, L. E., et al., "Patients with Amyotrophic Lateral Sclerosis and Other Neurodegenerative Diseases Have Increased Levels of Neurofilament Protein in CSF," Journal of Neurochemistry, Vol. 67, pp. 2013-2018 (1996)	

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			BY APPLICANT	Filing Date	July 29, 2003	
(Use as many sheets as necessary)				First Named Inventor	Bengt-Ake Bengtsson	
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	C58	Rossi, P., et al., "Acute Challenge with Apomorphine and Levodopa in Parkinsonism," European Neurology, Vol. 43, pp. 95-101 (2000)	
	C59	Schrag, A., et al., "Clinical Usefulness of Magnetic Resonance Imaging in Multiple System Atrophy," Journal Of Neurology Neurosurg. Psychiatry, Vol. 65, pp. 65-71 (1998)	
	C60	Singh, R. N. P., et al., "Modified Forms of Human Growth Hormone with Increased Biological Activities," Endocrinology, Vol. 94, No. 3, pp. 883-891 (1974)	
	C61	Smith, R. G., et al., "A Nonpeptidyl Growth Hormone Secretagogue," Science, Vol. 260, pp. 1640-1643 (1993)	
	C62	Smith, T. F., et al., "Comparison of Biosequences," Advances in Applied Mathematics, Vol. 2, pp. 482-489 (1981)	
	C63	Tannenbaum, G., "Evidence for Autoregulation of Growth Hormone Secretion Via The Central Nervous System," Endocrinology, Vol. 107, No. 6, pp. 2117-2120 (1980)	
	C64	Thorlacius-Ussing, O., "Zinc in the Anterior Pituitary of Rat: A Histochemical and Analytical Work," Neuroendocrinology, Vol. 45, pp. 233-242 (1987)	
	C65	Thorner, M. O., et al., "Growth Hormone-Releasing Hormone and Growth Hormone-Releasing Peptide as Therapeutic Agents to Enhance Growth Hormone Secretion in Disease and Aging," Recent Progress in Hormone Research, Vol. 52, pp. 215-246 (1987)	
	C66	Wenning, G. K., et al., "Minimal Change Multiple System Atrophy," Movement Disorders, Vol. 9, No. 2, pp. 161-166 (1994)	
	C67	Wenning, G. K., et al., "Multiple System Atrophy: A Review of 203 Pathologically Proven Cases," Movement Disorders, Vol. 12, No. 2, pp. 133-147 (1997)	

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STATEMENT BY APPLICANT	Filing Date	July 29, 2003	
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	C68	Wenning, G. K., et al., "Olivopontocerebellar Pathology in Multiple System Atrophy," Movement Disorders, Vol. 11, No. 2, pp. 157-162 (1996)		

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